

REMARKS

The Office is objecting to the claims for identifying element numbers in an improper format. Applicants note that the element numbers of claims 32 to 36 are in the proper format, i.e., enclosed in parentheses. Nevertheless, the claims have been amended to delete the element numbers. In view of the deletion of the element numbers, "tube", i.e., tube 4, has been amended to --guide wire tube-- to ensure definiteness of claim language. Removal of the objection to the claims is believed to be in order and is respectfully requested.

The Office states that in order "to claim benefit of a prior-filed application under 35 U.S.C. 119 or 120, a specific reference to the prior-filed application in compliance with 37 C.F.R. 1.78(a) must be included in the first sentence of the specification following the title or in an application data sheet." The Office then identifies the requirements for filing a petition for a delayed claim to priority.

It is unclear why such information is included in the present action. A statement in compliance in 37 C.F.R. 1.78(a) is required in the specification only if priority is claimed under 35 U.S.C. 120 or 35 U.S.C. 119(e). Such a statement is not required in the present application since only priority under 35 U.S.C. 119 of

foreign applications, Japanese patent application Nos. 2002-187145, 2002-346852, 2002-354671 and 2003-019141, is claimed.

A separate claim to priority and certified copies of the priority applications have been submitted to the USPTO in compliance with the requirements of 35 U.S.C. 119 and 37 C.F.R. 1.55. The Office has not identified any deficiencies in the claim to priority filed in the present application, and, according to applicants' review of USPTO records in the PAIR system, all materials are available in the Image File Wrapper of the application.

No action or amendment to the specification is believed to be required in connection with this matter. Applicants respectfully request that the Office indicate that the applicants have complied with the requirements of 35 U.S.C. § 119 and that the Office kindly acknowledge receipt of the certified copies of the priority documents.

Claims 2, 4-6, 9, 11, 13-15, 17, 21, 22, 24 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Maginot et al. (U.S. Patent No. 6,190,371) (hereinafter: "Maginot"). The Office states that Maginot discloses a multi-lumen catheter comprising an outer tube, inner tubes, lumina, lumen ports, a

tapered distal end and catheter tubes that are movable to close off blood ports.

Applicants respectfully submit that Maginot fails to disclose each and every element of the present invention and, therefore, fails to support a case of anticipation under 35 U.S.C. 102.

First, the guide catheter and guide lumen of Maginot are not equivalent to the outer tube of the present application which contains an inner cavity constituting a blood extraction lumen. The guide catheter of Maginot contains within its guide lumen a working catheter having an ingress lumen and an egress lumen. The advancement of fluid is carried out in the lumina of the working catheter. (see col. 8, lines 42 to 47). Fluid, e.g., blood, is neither extracted nor returned via the lumen of the guide catheter of Maginot. Furthermore, the catheter of Maginot contains a distal valve and a proximal valve to inhibit fluid from advancing into the guide lumen. (see col. 8, lines 15 to 23). Therefore, the guide lumen of Maginot is not a blood extraction lumen and cannot properly be interpreted as such.

Notwithstanding that 2, 4-6, 9, 11, 13-15, 17, 21, 22, 24 and 25 in their original form cannot be properly interpreted as reading on the device of Maginot, claims 2 and 4 of the application have been amended for clarity by reciting that the blood extraction

lumen is defined by the inner surface of the outer tube and the outer surfaces of the inner tube and the guide wire tube. Such amendment finds proper support, inter alia, in Figures 3 and 5-7.

Second, the Office alleges that a guide wire can be inserted into any of the lumina of Maginot, thus meeting the requirements of the claims of the present application. However, Maginot does not disclose a lumen for inserting a guide wire independent of the blood flow lumina. Maginot discloses only that the catheter is inserted into a vein by the tunneled catheter technique wherein the catheter is inserted after the insertion of a guide wire. (see col. 10, line 43, to col. 11, line 33). However, the claims of the present application require a separate structure, i.e., tube 4 (now --guide wire tube--), for inserting a guide wire into the catheter. The tube for inserting a guide wire does not share a common lumen with the blood extraction lumen or blood return lumen.

Furthermore, a guide wire cannot be inserted into a lumen that is in use during hemodialysis. During hemodialysis, the lumen for inserting a guide wire in the present application is not involved in blood extraction and infusion and, as a result, can be used for other functions such as an emergency injection of X-ray contrast medium or insertion of the guide wire for advancement of the catheter during hemodialysis. If a guide wire is inserted into a

lumen of the catheter of Maginot, that lumen cannot be used in hemodialysis while the guide wire is in place.

The features described above are present in independent claims 2 and 4 of the present application. Such features are not present in the catheter of Maginot and Maginot does not anticipate claims 2 and 4. Claims 5, 6, 9, 11, 13 to 15, 21, 22, 24 and 25 depend directly or indirectly on claim 4 and are *prima facie* patentable.

Removal of the 35 U.S.C. 102 rejections of the claims is believed to be in order and is respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated September 7, 2006, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

PATENT APPLN. NO. 10/606,374
RESPONSE UNDER 37 C.F.R. §1.111

**PATENT
NON-FINAL**

In the event any additional fees are required, please also
charge our Deposit Account No. 111833.

Respectfully submitted,
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